

CLAIM AMENDMENTS

1 1. (Currently amended) A pharmaceutical formulation,
2 packaged into a sachet and administered orally after dispersing in
3 water at therapeutic doses which comprises: [[of,]]

4 [[a.]] (a) alendronate microparticles coated with a
5 polymer insoluble at pH 6 - 7.5, and alginic acid or sodium
6 alginate or admixtures thereof in an amount therapeutically
7 effective to prevent esophageal reflux, heartburn and esophagitis
8 in a patient taking alendronate, where

9 [[b.]] (b) alendronate dissolves in 900 ml 0.1 N HCl at
10 the rate of not less than 85% of within 30 minutes at the range of
11 pH 1 - 4,

12 [[c.]] (c) the dispersion in a glass of 250 ml. water at
13 the degree of 25°C contains no dissolved alendronate at pH 6 - 7.5
14 or at the most 10% w/v of alendronate dissolved in 3 minutes.

1 2. (original) The pharmaceutical formulation as claimed
2 in claim 1, comprises lubricants, diluents, flavors and sweeteners
3 or their mixture thereof.

1 3. (currently amended) The pharmaceutical formulation as
2 claimed in claim 2, where in the diluent is preferably selected
3 from the group consisting of lactose and microcrystalline cellulose
4 or admixtures thereof.

1 4. (Currently amended) The pharmaceutical formulation as
2 claimed in claim 2, where in the sweetener is selected from the
3 group consisting of aspartame, potassium acesulfame, monoammonium
4 glycyrrhizinate, sodium saccharine, sucrose and ~~its derivatives,~~
5 ~~polyols and their derivatives,~~ are preferably used alone or in
6 combination.

1 5. (Currently amended) The pharmaceutical formulation as
2 claimed in claim 1, where in the ~~polymers are~~ polymer is selected
3 from the group consisting of , preferably polymethacrylates,
4 polyvinyl acetate diethylaminoacetate and poly butyl methacrylate /
5 2-dimethylamino-ethyl methacrylate/methyl methacrylate copolymers
6 or their mixtures thereof.

1 6. (Currently amended) The pharmaceutical formulation as
2 claimed in claim 1, where in the ~~polymers are,~~ polymer is
3 Poly(butyl methacrylate, (2-dimethyl aminoethyl) methacrylate,
4 methyl methacrylate) in a ratio of 1:2:1 is preferred.

1 7. (original) The pharmaceutical formulation as claimed
2 in claim 1, which is dispersed in a glass of 250 ml water at the
3 degree of 25°C at pH 6 - 7.5, contains alendronate in between
4 0.001% w/v - 3% w/v.

1 8. (Currently amended) The pharmaceutical formation
2 formulation as claimed in claim 1 where in the alendronate is
3 alendronate monosodium trihydrate ~~or pharmaceutically acceptable~~
4 derivatives.

1 9. (original) The pharmaceutical formulation as claimed
2 in claim 1, which is dispersed in a glass of 250 ml. water at the
3 degree of 25°C at pH 6 - 7.5, contains alginic acid or sodium
4 alginate or their mixtures in between 0.001% w/v - 2% w/v.

1 10. (Currently amended) A pharmaceutical formulation,
2 which is packaged into a sachet and orally administered after
3 dispersing in water, which comprises consists essentially of:
4 alendronate microparticles coated with a polymer insoluble at pH 6
5 to 7.5, wherein the polymer comprises polybutyl methacrylate,
6 (2-dimethylaminoethyl)methacrylate and methyl methacrylate in a
7 1:2:1 ratio; alginic acid or sodium alginate or admixtures thereof
8 in an amount therapeutically effective to prevent esophageal
9 reflux, heartburn and esophagitis in a patient taking alendronate;
10 sucrose and sodium saccharine as sweeteners; microcrystalline
11 cellulose as diluent; and colloidal silica as a lubricant, wherein
12 the alendronate dissolves in 900 ml of 0.1N HCl at a rate of not
13 less than 85% within 30 minutes at a pH of 1 to 4, and wherein the
14 resulting dispersion in water at 25°C contains either no dissolved

- 15 alendronate at a pH of 6 to 7.5, or at most 10% w/of dissolved
16 alendronate after 3 minutes.